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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,805	10/12/2001	Maximilian Polyak	053137-5002-01	2437

7590 01/08/2003
MORGAN, LEWIS & BOCKIUS LLP
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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/08/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/976,805

Applicant(s)
Polyak et al.

Examiner
Sandra Saucier

Art Unit
1651



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-28 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-28 are pending and subject to restriction.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-5, 9-12, 20 drawn to a first solution comprising prostaglandin, NO donor, glutathione precursor, classified in class 435, subclasses 1.1, 1.2, 1.3, 2 and others.
- II. Claim 6, drawn to a second solution comprising prostaglandin, NO donor, glutathione precursor KH_2HPO_4 , sodium gluconate, magnesium gluconate, adenine and ribose, classified in class 435, subclasses 1.1, 1.2, 1.3, 2 and others.
- III. Claim 7, drawn to a third solution comprising prostaglandin, NO donor, glutathione precursor, CaCl_2 , HEPES, glucose, mannitol and pentastarch classified in class 435, subclasses 1.1, 1.2, 1.3, 2 and others.
- IV. Claim 8, drawn to a fourth solution comprising prostaglandin, NO donor, glutathione precursor, NaCl and KOH classified in class 435, subclasses 1.1, 1.2, 1.3, 2 and others .
- V. Claim 13-17, drawn to a fifth composition comprising prostaglandin, NO donor, glutathione precursor, and an organ or tissue, classified in class 435, subclasses 1.1, 1.2, 1.3, 2 and others.
- VI. Claims 18 and 19, drawn to an apparatus, classified in 435, subclass 284.1.
- VII. Claims 21-25, drawn to a method of using a perfusion solution comprising prostaglandin, NO donor and a glutathione precursor, classified in 435, subclasses 1.1, 1.2, 1.3, 2 and others.

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VIII. Claims 26-28, drawn to a method of making a solution comprising mixing sodium gluconate, potassium phosphate, adenine, ribose, calcium chloride etc., classified in 435, subclasses 1.1, 1.2, 1.3, 2 and others.

Claim 1 is generic to Group I, II, III, IV, V and VI and will be examined with the elected group.

The inventions are distinct, each from the other because of the following reasons:

Group I does not require the components of Groups II, III, IV, V or VI and is therefore, a distinct composition.

For example, a composition A may not be restricted from compositions A+B, or from A+B+C, or from A+B+C+D as these form a tree of further limitations. However, compositions A+B and A+C and A+D, etc. are distinct compositions and may be properly restricted.

Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, (2), the product may be used in a static fashion, that is without the perfusion machine, to immerse a tissue or organ as is routine in the transplantation field.

Invention VII is a method of making a solution. Once an allowable solution is determined, claims directed to methods of making that allowable solution can be rejoined upon the request of the applicant.

A method of using the allowable solution may also be rejoined upon the request and submission of appropriate claims by the applicant as long as no issues of new matter are raised.

The processes are distinct from one another because they recite different and distinct steps which lead to different and distinct products.

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The several inventions listed above are independent and distinct from one another as they have acquired a separate status in the art and require independent searches, particularly with regard to the literature searches. Clearly, a reference which would anticipate one of the above groups would not necessarily anticipate or even make obvious any of the others.

An undue burden would ensue from the examination of multiple compositions and methods which have distinct components, steps and end points. Burden lies not only in the search of US Patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement.

Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 5:00PM Monday and Tuesday and 8:30 to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number

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of the Fax Center for the faxing of papers is (703) 308-2742 or (703) 305-3592.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized flourish at the end.

Sandra Saucier
Primary Examiner
Art Unit 1651
December 30, 2002